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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

TON, THAIAN N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1632

DATE MAILED: 11/04/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/614,326

Applicant(s)

EDELBERG ET AL.

Examiner

Thaia N. Ton

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 September 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 27 September 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: 76 and 77.

Claim(s) objected to: _____.

Claim(s) rejected: 27,29,30,32,33,43,45,52,53,57,69-75 and 78-86.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/630

Continuation of 2. NOTE: The proposed amendments raise issues that would require further search and consideration with regard to the recitation of "upregulating heart rate" [see claim 33, 69, 70, for example] .

Continuation of 5. does NOT place the application in condition for allowance because: With regard to the rejection over 112, 1st paragraph, Applicants argue that the specification provides support for regulation and altering cardiac rhythm in vivo as well as ex vivo. Applicants argue that the Examiner has ignored Applicants claimed invention [methods to upregulate heart rate or alter cardiac rhythm] and broadly confers subject matter in the specification that was not explicitly claimed. Applicants argue that because there is no "therapeutic result" language in the claims, it is improper for the Examiner to import such language from the specification. Applicants point out that the claims are directed to "upregulating heart rate" and "altering cardiac rhythm". [See pp. 5-7 of the Response].

The prior rejection is reiterated for reasons of record advanced on pages 2-6 of the prior Office action. In particular, it is reiterated that the mere showing of the upregulation of heart rate or altered cardiac rhythm does not enable the claimed invention because the intended use of the claimed invention is directed to methods of treatment [see p. 4 1st paragraph of the prior Office action]. As such, it is reiterated that the state of the art of gene therapy is unpredictable, as advanced on pages 5-6 of the prior Office action. Applicants argue that the data disclosed in the examples enable the claimed invention because the Yorkshire pig used in the examples is an art-recognized model for the human cardiovascular system. It is reiterated [see pp. 5-6 of the prior Office action] that the Yorkshire pig disclosed by Applicants cannot be a model for diseases involving cardiac conductive tissue incompetence, as the pig has no disease representative of cardiac conductive tissue incompetence.

The prior rejections under 102 and 103 are withdrawn in view of Applicants' arguments and/or amendments to the claims.